Sustainability Report

Our goal at STAAR Surgical Company is to become the primary and premium option for people seeking visual freedom, and to become the best partner for our surgeon customers. We seek to achieve these goals in a respectful and sustainable manner with regards to our stakeholders, including investors, business partners, employees, and our communities. Consistent with the Sustainability Accounting Standards Board's framework of sustainability topics for medical equipment and supplies companies, we are providing the following information relating to our business:

Affordability and Pricing:

We did not increase the price of our ICLs or IOLs in 2019 despite an increase in the Consumer Price Index of 2.3%.

We generate approximately 86% of our global revenue from sales of our EVO Visian ICL family of lenses. The ICL is considered a patient cash-pay, non-reimbursable medical device. We generate approximately 11% of our global revenue from sales of our IOLs. Our IOL products are generally reimbursable, and have historically faced pricing pressures from the market.

In countries where we sell our medical devices directly to customers (e.g., ophthalmologists and medical clinics where ophthalmologists work), we sell based on established price structures for the specific country where the customer works. Such pricing varies by volume purchased and geographic location. In countries where we sell our medical devices indirectly via distributors, our distributors establish their own pricing. In hybrid markets where we engage employees of STAAR to work together with distributors to train, promote and sell our medical devices, we collaborate with distributors in establishing pricing structures for certain strategic and alliance customers. In the U.S., a direct market, the volume-based list price for our products is publicly available to customers trained and certified to purchase and implant our medical devices. For competitive purposes, the terms and conditions of our strategic and alliance agreements in all markets, including pricing and commitment to training and patient education, among other terms, are not publicly disclosed.

Product Safety:

Like all medical devices, implanting our medical devices may result in possible adverse events. As an implanted medical device, we impose stringent quality standards on our manufacturing and finished goods processes. Despite our Quality Management System efforts, it is possible for a medical device to not meet our standards, or the standards of a regulatory agency, and result in a product recall.

In 2019, (i) none of our products were recalled in the U.S. or internationally, (ii) none of our products were listed on the FDA's MedWatch Safety Alerts for Human Medical Products database, (iii) none of our products caused fatalities as reported in the FDA Manufacturer and User Facility Device Experience, or elsewhere internationally, and (iv) we did not receive any FDA or other Health Authority enforcement actions taken in response to alleged or actual violations of current Good Manufacturing Practices or Quality System requirements.

Ethical Marketing:

STAAR's employees must comply with our Compliance Program for Interactions with Healthcare Professionals. The Program prohibits, among other things, promoting our medical devices "off-label" (i.e., for any unapproved use). We provide online and in-person training regarding ethical sales practices to applicable employees. We prohibit the promotion of our medical devices for any unapproved use, pursuant to the Food, Drug and Cosmetic Act and applicable international regulations. Failure to comply with the Program may result in disciplinary action, including termination. Also, representatives from our Medical, Legal and Regulatory departments review promotional material prepared by the Marketing department to assess the permissibility of claims regarding safety, efficacy and other matters.

In 2019, we did not face any legal proceedings associated with false marketing claims, and as such did not incur any monetary losses as a result thereof.

Product Design & Lifecycle Management:

We endeavor to minimize our environmental footprint while balancing such concerns with regulatory requirements and operational considerations. We continuously seek to improve the efficiency of our manufacturing efforts and reduce the resources, including energy and water use, needed to produce our medical devices. Our on-going projects include a project to reduce the size and material in our product packaging. By 2020, we expect to complete our project to eliminate the application of adhesives in our product final packaging, substituting foldable flaps and a small seal at the close flap. This should reduce both the overall consumption of adhesives in our manufacturing process, as well as reduce waste in products sent to our customers.

Slightly smaller in size than a contact lens, our ICL lenses are designed to provide vision correction and intended to remain in place as long as the patient is satisfied with his or her vision. The lenses are removable if the patient is not happy, or develops a cataract as part of the normal aging process. We expect our lenses will remain implanted in a patient for many years. On the other hand, people using contact lenses must dispose of their contact lenses after use (either daily or monthly, etc., depending on the type of contact lens). We have engaged researchers at a university to determine whether the ICL has a smaller environmental impact than contact lenses over the course of time a person would use either device.

We are mindful of our employees' safety during the manufacturing of our medical devices. The Workers' Compensation Insurance Rating Bureau of California assessed us with an Experience Modification of 58%. An Experience Modification is a percentage that compares the payroll and loss history of a company to those of similar-sized companies in the same industry. For example, if a company has a better than average loss record, their experience modification would be less than 100%. Generally, an experience modification of less than 100% reflects better-than-average injury experience, while an experience modification of more than 100% reflects worse-than-average injury experience. The experience modification formula can be found in the *California Workers' Compensation Experience Rating Plan - 1995*. Normally, an experience modification is calculated based on the actual audited payroll and losses reported by the insurer (STAAR) for three consecutive policy years.

Our medical devices, intraocular lenses, cannot be reused or donated after implantation into a patient. Given the limited number of lenses explanted annually, the small size of each lens, and the potential health hazard considerations with the additional handling of a lens explanted from a patient's eye, together with the environmental impact of packaging then mailing or shipping back a lens to us for recycling, we do not offer recycling of lenses explanted in the ordinary course of the practice of medicine. As to recycling, we provide recycling bins at our facilities for use by our employees.

We receive requests to donate lenses to assist with the vision needs of patients domestically and internationally who cannot afford to purchase vision correction medical devices. We evaluate each request and donate lenses as circumstances and our budget permits.

Supply Chain Management:

Our facilities participate in regular third-party audit programs such as ISO13485 or FDA Code of Federal Regulations (CFR) 820 by various regulatory agencies such as the FDA, DEKRA (our European Notified Body), Japan's PMDA, and Health Canada. Also, we operate an audit program of our suppliers. We classify our suppliers according to product risk, which then determines the frequency we visit the suppliers' facility or conduct desk audits. We sell a class III medical device so certain suppliers must maintain their own Quality Management System and comply with international regulations and standards including the FDA CFR 820 and ISO 13485. Our audits are intended to determine, among other things, our suppliers' compliance to their quality management system. Most of our Tier I (i.e., highest risk) suppliers participate in external agency audits by a recognized international regulatory agency such as FDA, USDA (US Department of Agriculture), or ISO (International Standards Organization). Of our Tier 1 suppliers that in aggregate account for approximately 90% of our annual supply purchases, approximately 87% are subject to third party audit programs.

We maintain procedures and systems to provide product traceability and identification regarding the following stages of manufacture and distribution:

- raw material and component receipt;
- manufacturing, assembly, testing, labeling, and packaging;
- finished goods warehousing; and
- delivery to the customer.

Our processes include issuance of part numbers for incoming materials and components to establish backward traceability. For each Class III implantable lens medical device, we automatically generate unique serial numbers to establish forward traceability. For non-Class III medical devices, we maintain lot number traceability to establish forward traceability. Individual material part numbers can be forward traced for all medical devices, and likewise all medical devices can be backward traced to individual part numbers.

We also use work orders for all medical devices to document traceability. Our electronic Enterprise Resource Planning (ERP) system generates unique serial numbers and maintains transactional information regarding medical devices as well. We use bar code scanning during labeling and final packaging for our medical devices. Finally, our ERP system generates Unique Device Identifiers (UDI) for medical devices to further enhance traceability at delivery of the product to the customer.

We do not believe we are subject to a material risk related to the use of critical materials, with respect to availability or changes in price. Our most critical material is Collamer which we manufacture ourselves. The component parts of Collamer do not include rare earth elements or platinum group metals (as defined in the U.S. National Research Council of the National Academies' "Minerals, Critical Minerals, and the U.S. Economy").

We use a small number of critical raw materials in other aspects of our manufacturing processes. For these critical raw materials (which cannot be disclosed for competitive reasons), we take the following steps to reduce the risk of supply disruption: (1) specification review to minimize the number of critical raw materials and quantity of such materials used; (2) supplier selection review to identify and assess supplier qualifications; and (3) supplier risk management, using a scoring system for suppliers of critical materials and components using a variety of metrics to calculate the overall risk for each supplier. We manage each supplier according to the risk matrix to reduce the risk of supply disruption. Finally, for supplier quality management, we use a system based on assessed risk, with follow-up actions ranging from supplier audits to possible supplier correction requests in the event of quality issues.

Business Ethics:

In 2019, we did not face any legal proceedings associated with bribery or corruption, and as a result we did not incur any monetary losses related thereto.

STAAR's employees must comply with our Code of Business Conduct and Ethics. The Code prohibits, among other things, any transfer of value to obtain an improper advantage. As noted above, our employees must also comply with our Compliance Program for Interactions with Healthcare Professionals ("Program"). Our interactions with Healthcare Professionals are intended to benefit patients and to enhance the practice of medicine by providing STAAR-approved scientific and educational information about our medical devices. The Program includes limits to amounts an employee may spend on meals while meeting with a Healthcare Professional, and restrictions on entertainment, among other things. The Program also underscores the importance of ethical business practices and the avoidance of interfering with a Healthcare Professional's independent judgment. Our Internal Audit function assists with reviewing compliance with these policies and programs. We provide online and in-person training regarding our Code to employees. We also maintain a Supplier Code of Conduct that applies to our vendors.